CURRENT STATUS OF THE CLAIMS

In the Claims

The following is a marked-up version of the claims with the language that is underlined ("___") being added and the language that contains strikethrough ("—") being deleted:

1. (Currently amended) An oral pharmaceutical composition comprising multiple populations of at least one of beads, pellets, tablets and granules provided in a capsule, the composition comprising:

(i) a first population of a pharmaceutical active comprising a pharmaceutical active substance releasable at a first rate;

(ii) a population of a basic substance; and

(iii) a second population of a pharmaceutical active comprising a pharmaceutical active substance releasable at a second rate[[.]];

wherein (i), (ii), and (iii) are three distinct populations.

2. (Previously presented) The composition of claim 1, wherein the first rate of release is faster than the second rate of release.

3. (Previously presented) The composition of claim 1, wherein the second rate of release is release in at least one of a delayed and sustained manner.

4. (Previously presented) The composition of claim 1, further comprising a third population of a pharmaceutical active comprising a pharmaceutical active substance being releasable at a third rate.

5. (Previously presented) The composition of claim 4, wherein the first rate of release is a release in a rapid manner, the second rate of release is release in at least one of a delayed and sustained manner, and the third rate of release is release in at least one of a delayed and sustained manner.

6. (Previously presented) The composition of claim 1, wherein the oral pharmaceutical composition is a pulsed release capsule.

7. (Previously presented) The composition of claim 1, wherein at least one of (i), (ii) and (iii) further comprise at least one excipient.

8. (Previously presented) The composition of claim 7, wherein said at least one excipient is selected from the group consisting of binders, surfactants, fillers, lubricants, disintegrating agents, sustained release agents, and combinations thereof.

9. (Previously presented) The composition of claim 7, wherein said at least one excipient of (i) to (iii) is present in an amount of about 0.5% to about 95% by weight of said beads, pellets, tablets or granules of said population.

10. (Previously presented) The composition of claim 7, wherein said at least one excipient of (iii) is a sustained release agent.

11. (Previously presented) The composition of claim 7, wherein said at least one excipient of (i) serves to release the pharmaceutical active substance of the first population faster than the pharmaceutical active substance of the second population.

12. (Previously presented) The composition of claim 11, wherein said at least one excipient of (i) is a disintegrating agent.

13. (Previously presented) The composition of claim 1, wherein the pharmaceutical active of (iii) further comprises an enteric coating.

14. (Previously presented) The composition of claim 13 wherein a separating layer is provided to separate the pharmaceutical active of (iii) from contact with the enteric coating.

15. (Previously presented) The composition of claim 1 further comprising (iv) a population of a basic substance, wherein the basic substance is released slower than the basic substance of (ii).

16. (Previously presented) The composition of claim 15, wherein the basic substance of (iv) further comprises an enteric coating.

17. (Previously presented) The composition of claim 16, wherein a separating layer is provided to separate the basic substance of (iv) from contact with the enteric coating.

18. (Previously presented) The composition of claim 1, wherein the pharmaceutical active substance of the first population is the same as the pharmaceutical active substance of the second population.

19. (Previously presented) The composition of claim 1, wherein at least one of the pharmaceutical active substances of (i) and (iii) comprises an acid labile drug.

20. (Previously presented) The composition of claim 19, wherein said at least one of the pharmaceutical active substances of (i) and (iii) comprises at least one of a proton pump inhibitor, a prodrug of a proton pump inhibitor, a single enantiomer of a proton pump inhibitor, a single enantiomer of a prodrug of a proton pump inhibitor, and combinations thereof.

21. (Previously presented) The composition of claim 1, wherein said basic substance is selected from the group consisting of sodium, potassium, calcium, magnesium and aluminum salts of phosphoric acid, carbonic acid, and citric acid; aluminum hydroxide; sodium bicarbonate; aluminum, calcium and magnesium hydroxides; magnesium oxide; trihydroxymethylaminomethane; basic amino acids or their salts; and mixtures thereof.

22. (Previously presented) The composition of claim 1, wherein (i) provides delivery of the pharmaceutical active to the stomach upon oral administration.

23. (Previously presented) The composition of claim 1, wherein (iii) provides delivery of the pharmaceutical active between the duodenum and just past the ileocecal junction.

24. (Previously presented) The composition of claim 1, wherein (ii) is rapidly released in the stomach and increases the stomach pH to more than about 4 and less than about 7 in less than about 1 hour, wherein the pharmaceutical active of (i) is rapidly or gradually released in the stomach.

25. (Currently amended) The composition of claim ~~24~~ 13, wherein (ii) is rapidly released in the stomach and increases the stomach pH to more than about 4 and less than about 7 in less than about 1 hour, wherein the pharmaceutical active of (i) is rapidly or gradually released in the stomach.

26. (Previously presented) The composition of claim 15, wherein (ii) is rapidly released in the stomach and increases the stomach pH to more than about 4 and less than about 7 in less than about 1 hour, wherein the pharmaceutical active of (i) is rapidly or gradually released in the stomach, (iii) provides delivery of the pharmaceutical active between the duodenum and just past the ileocecal junction, and (iv) releases said basic substance just past the ileocecal junction.

27. (Previously presented) The composition of claim 8, wherein said sustained release agents are selected from the group consisting of pectin, polyvinyl alcohol, polyvinyl acetate, hydroxypropyl cellulose, methylcellulose, ethylcellulose, hydroxypropyl methylcellulose, carragenan, xanthan gum, carbomer and mixtures thereof.

28. (Previously presented) The composition of claim 8, wherein said disintegrating agents are selected from the group consisting of homopolymer cross-linked N-vinyl-2-pyrrolidone, sodium starch glycolate, cross-linked sodium carboxymethylcellulose and mixtures thereof.

29. (Withdrawn) A method for treating conditions caused by inappropriate gastric acid secretion, said method comprising administering the composition of claim 49 to a subject in need of such treatment.

30. (Withdrawn) The method of claim 29, wherein said inappropriate gastric acid secretion is night time acid secretion and said administration is done at night time.

31. (Currently amended) An oral pharmaceutical composition comprising multiple populations of at least one of beads, pellets, tablets and granules provided in a capsule, the composition comprising:

(i) a population of a pharmaceutical active;

(ii) a population of a basic substance;

(iii) a population of enteric coated pharmaceutical active; and

(iv) a population of enteric coated basic substance[[.]];

wherein (i), (ii), (iii), and (iv) are four distinct populations.

32. (Previously presented) The composition of claim 31, wherein a separating layer is provided to said population of enteric coated pharmaceutical active, said separating layer being provided to separate said pharmaceutical active from contact with said enteric coating.

33. (Previously presented) The composition of claim 31, wherein a separating layer is provided to said population of enteric coated basic substance, said separating layer being provided to separate said basic substance from contact with said enteric coating.

34. (Previously presented) The composition of claim 31, wherein at least one excipient is provided to at least one of (i) to (iv).

35. (Previously presented) The composition of claim 34, wherein said at least one excipient is selected from the group consisting of binders, surfactants, fillers, lubricants, disintegrating agents, sustained release agents, and combinations thereof.

36. (Previously presented) The composition of claim 34, wherein said at least one excipient is present in an amount of about 0.5% to about 95% by weight of said beads, pellets, tablets or granules of said population.

37. (Previously presented) The composition of claim 31, wherein at least one over-coating layer is provided to at least one of said population of (i) to (iv).

38. (Previously presented) The composition of claim 31, wherein said pharmaceutical active comprises an acid labile drug.

39. (Previously presented) The composition of claim 38, wherein said pharmaceutical active comprises a proton pump inhibitor, a prodrug of a proton pump inhibitor, a single enantiomer of a proton pump inhibitor, a single enantiomer of a prodrug of a proton pump inhibitor, and combinations thereof.

40. (Previously presented) The composition of claim 31, wherein said basic substance is selected from the group consisting of sodium, potassium, calcium, magnesium and aluminum salts of phosphoric acid, carbonic acid, and citric acid; aluminum hydroxide; sodium bicarbonate; aluminum, calcium and magnesium hydroxides; magnesium oxide; trihydroxymethylaminomethane; basic amino acids or their salts; and mixtures thereof.

41. (Previously presented) The composition of claim 40, wherein said basic substance is calcium carbonate.

42. (Previously presented) The composition of claim 31, wherein said population of any one of (i) to (iv) is made by extrusion pheronization or compression into tablets.

43. (Previously presented) The composition of claim 31, wherein (i) begins delivery of said active in the stomach upon oral administration.

44. (Previously presented) The composition of claim 31, wherein (i) provides delivery of said active to the stomach, (iii) provides delivery of said active between the duodenum and just past the ileocecal junction and (iv) provides delivery of said active to the ascending, transverse and descending colon.

45. (Previously presented) The composition of claim 31, wherein (ii) is rapidly released in the stomach and increases the stomach pH to more than about 4 and less than about 7 in less than 1 hour, wherein (i) is rapidly or gradually released in the stomach, (iii) provides rapid or gradual release of active between the duodenum and just past the ileocecal junction and (iv) releases said basic substance just past the ileocecal junction.

46. (Withdrawn) A method for treating conditions caused by inappropriate gastric acid secretion, said method comprising administering the composition of claim 79 to a subject in need or such treatment.

47. (Withdrawn) The method of claim 46, wherein said inappropriate gastric acid secretion is night time acid secretion and said administration is done at night time.

48. (Withdrawn) A method for making the composition of claim 31, said method comprising;

(a) providing a pharmaceutical active or basic substance to a core material to provide a population of (i) and (iii);

(b) providing one or more enteric coating layers to a portion of (a); and

(c) providing (a) and (b) within a capsule.